



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/585,964	07/13/2006	Chudi Guan	NEB-236-PUS	7911
28986	7590	10/21/2008		
HARRIET M. STRIMPEL, D. Phil. New England Biolabs, Inc. 240 COUNTY ROAD IPSWICH, MA 01938-2723			EXAMINER RAMIREZ, DELIA M	
			ART UNIT 1652	PAPER NUMBER
			NOTIFICATION DATE 10/21/2008	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

STRIMPEL@NEB.COM  
Goldberg@neb.com  
wermuth@neb.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/585,964	<b>Applicant(s)</b> GUAN ET AL.	
	<b>Examiner</b> DELIA M. RAMIREZ	<b>Art Unit</b> 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-31 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____.                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____.  | 6) <input type="checkbox"/> Other: ____.                          |

Art Unit: 1652

## **DETAILED ACTION**

### ***Status of the Application***

Claims 1-31 are pending.

### ***Election/Restrictions***

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-17, 24, 26-28, 31, drawn in part to a modified DNA cleaving enzyme having 35% sequence identity with T7 Endo I, wherein said enzyme has a mutation in the beta bridge that separates the two catalytic centers, a kit comprising said enzyme, and a method of use of said enzyme to detect single nucleotide polymorphisms.

Group II, claim(s) 18-23, 24, drawn in part to a nucleic acid which substantially corresponds to SEQ ID NO: 1 that has at least one mutation in the sequence corresponding to a beta bridge, vectors, and host cells comprising said nucleic acid, a method to recombinantly produce a protein encoded by said nucleic acid, and a kit comprising said nucleic acid, host cells or vectors.

Group III, claim(s) 25, drawn to a method for modifying enzyme catalytic activity.

Group IV, claim(s) 29, drawn to a method of forming a shotgun cloning library.

Group V, claim(s) 30, drawn to a method for mapping nicks in a duplex DNA.

2. The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

3. The protein of Group I and the methods of Group IV-V while being combinations comprising a product and a process of use of said product, do not have unity of invention according to 37 CFR 1.475(b) since Group I (main invention) already contains one of the combinations set forth in 37 CFR 1.475(b),

Art Unit: 1652

i.e., a product and a process of use of said product, and the combinations of Group I and IV-V are additional combinations as set forth in 37 CFR1.475(b)(2).

4. According to PCT Rule 13.2 unity of invention exist only when there is a shared same or corresponding special technical feature among the claimed inventions. The nucleic acid of Group II and the methods of Groups III-V lack a shared same or corresponding special technical feature since the technical feature of Group II is a nucleic acid, the technical feature of Groups IV-V is a method of use of the protein of Group I, and the technical feature of Group III is a method for modifying enzyme catalytic activity. Therefore, none of these special technical features is shared by or corresponds to any of the inventions of Groups II, III, IV or V.

5. According to PCT Rule 13.2 unity of invention exist only when there is a shared same or corresponding special technical feature among the claimed inventions. The protein of Group I and the method of Group III lack a shared same or corresponding special technical feature since the technical feature of Group I is a protein, and the technical feature of Group III is a method for modifying enzyme catalytic activity. Therefore, none of these technical features is shared by or corresponds to any of the inventions of Groups I or III.

6. According to PCT Rule 13.2 unity of invention exist only when there is a shared same or corresponding special technical feature among the claimed inventions. The protein of Group I and the nucleic acid of Group II lack a shared same or corresponding special technical feature since the technical feature of Group I is a protein which is at least 35% amino acid sequence identical with T7 Endo I and has DNA cleaving activity, and the technical feature of Group II is a nucleic acid which substantially corresponds to the polynucleotide of SEQ ID NO:1. Since a nucleic acid encoding a protein of any function which substantially corresponds to the polynucleotide of SEQ ID NO: 1 does not have to encode a protein with DNA cleaving enzymatic activity and at least 35% sequence identical with T7 Endo I, the nucleic acid of Group II does not have to encode the protein of Group I and the protein of Group I

Art Unit: 1652

does not have to be encoded by the nucleic acid of Group II. Therefore, none of these technical features is shared by or corresponds to any of the inventions of Groups I or II.

7. The Examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

8. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

9. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention. The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the

Art Unit: 1652

election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention. If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention. Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

11. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (571) 272-0938. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM. If attempts to reach the examiner by telephone

Art Unit: 1652

are unsuccessful, the examiner's supervisor, Dr. Nashaat Nashed can be reached on (571) 272-0934. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

/Delia M. Ramirez/

Delia M. Ramirez, Ph.D.  
Primary Patent Examiner  
Art Unit 1652

DR  
October 18, 2008